DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 4, 2014

Brivant Limited
% Kenneth Walsh
Regulatory Affairs Group Leader
Parkmore West Business Park
Galway, Ireland

Re: K141831
Trade/Device Name: HydraView Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 4, 2014
Received: July 7, 2014

Dear Kenneth Walsh,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141831

Device Name
HydraView Polymer Guidewire

Indications for Use *(Describe)*
The HydraView Polymer Guidewires are intended for use in the coronary and peripheral vasculature to facilitate the selective placement of interventional devices with compatible guidewire lumen and compatible coronary venous leads.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Device Name	HydraView Polymer Guidewire
Submitters name	Brivant Limited, Parkmore West Business Park Galway, Ireland
Application Correspondent	Kenneth Walsh Regulatory Affairs Group Leader Lake Region Medical Limited Tel: +353 91 385037 Fax: +353 91 766598
Summary Preparation Date	4th July 2014
Device Name & Classification	Trade Name: HydraView Polymer Guidewire Common Name: Guidewire Classification Name: Catheter, Guidewire Device Classification: Class II, 21 CFR §870.1330 Product Code: DQX
Intended Use	Intended Use: The HydraView Polymer Guidewires are intended for use in the coronary and peripheral vasculature to facilitate the selective placement of interventional devices with compatible guidewire lumen and compatible coronary venous leads. Contraindications: The HydraView Polymer Guidewires are not intended for use in the cerebral vasculature. Patients judged not acceptable for percutaneous intervention.
Device Description	The HydraView Guidewire is a disposable medical device designed for single use only. It consists of a PTFE coated 190cm, 0.014" diameter stainless steel core wire, one end of which is reduced in diameter over a 30cm approx. segment in a progressive fashion through a centreless grinding operation. The profile of this reduced section affords the product a reduced area of stiffness and is varied to produce 3 unique levels of support; ES, DS and EDS.

Predicate Devices	**Device/Manufacturer**	**510k**	**Date**
	Streamer Guidewire/ Brivant Limited	K083094	7th July 2009
	Charter Guidewire/ Brivant Limited	K103377	18th May 2011

Principle of Operation	The HydraView guidewire is operated manually by a manual process
Comparison of Technological Characteristics	This HydraView Guidewire has the following differences from the primary predicate device: - Change in the polymer material at the distal tip of the device. - Minor dimensional changes to the tip profile. - Minor change to indications for use statement No other changes are proposed to the device. In vitro bench testing data is available to support a determination of substantial equivalence between the Hydraview Guidewire models and the predicate (refer to performance testing below). The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended

	use and performs comparably to the existing devices in the range. The Hydraview Guidewire design does not introduce any new issues of safety and effectiveness such that the proposed Hydraview Guidewire is considered substantially equivalent to the predicate devices.
Performance Testing (non-clinical)	In vitro bench tests were carried out to demonstrate equivalence of the modified design to the predicate marketed devices i.e Streamer and Charter with reference to the FDAs guidance document "Coronary and Cerebrovascular Guidewire Guidance, Jan 1995". The following bench tests were performed: - Dimensional Verification - Tensile Strength - Torque strength - Torque response/Torqueability - Coating adherence/Integrity - Catheter/Lead compatibility - Tip Stiffness - Biocompatibility testing - Radiopacity testing - Particulate Testing The results from these performance evaluations demonstrate the proposed HydraView design is substantially equivalent to the predicate Streamer Guidewire and that the materials of construction are identical to the predicate Charter Guidewire The changes made to the device do not raise any new questions regarding safety and effectiveness. Biological Safety of the device has been established through successful use of the same materials and manufacturing process in current 510(k) approved Lake Region Medical products.
Conclusions	Based on safety and performance testing, technological characteristics and the indications for use for the device, the HydraView Guidewire has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.